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| APPLICATION NO. | FILING DAT | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------------|-------------|----------------------|-------------------------|------------------|--|
| 09/911,051 07/23/2001 | | Weenna Bucay-Couto | 01-089 | 3728 | |
| 27774 | 7590 03/ | 2003 | | | |
| | ORTKORT & V | EXAMINER | | | |
| 2ND FLOOI | - | | SERKE, CATHERINE | | |
| WESTFIELI | O, NJ 07090 | | ART UNIT | PAPER NUMBER | |
| | | | 3763 | | |
| | | | DATE MAILED: 03/13/2003 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | mF | | | |
|---|--|------------------------|--|-------|--|--|--|
| | | 09/911,051 | BUCAY-COUTO E | T AL. | | | |
| Office Action Summary | | Examiner | Art Unit | | | | |
| | | Catherine Serke | 3763 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | | |
| Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | Decrees to communication(a) filed as 20.5 |) | | | | | |
| 1) 🖾 | Responsive to communication(s) filed on 20 E | | | | | | |
| 2a) 🗌 | ,— | s action is non-final. | | | | | |
| 3)[_] | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | | |
| 4) Claim(s) 1-31 is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) 8,13 and 14 is/are allowed. | | | | | | | |
| 6)⊠ Claim(s) <u>1,5,6,9-12,15,21,27 and 31</u> is/are rejected. | | | | | | | |
| 7)🖂 | Claim(s) <u>2-4,7,13,14,16-20,22-26 and 28-30</u> is/ | are objected to. | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Application | · | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | | |
| 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| 11)∐ The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a) All b) Some * c) None of: | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachment(s) | | | | | | | |
| 2) Notice | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s) | | (PTO-413) Paper No(s atent Application (PTO | | | | |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 21 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Smothers et al (US Pat# 2003/0036761).

Smothers discloses a medical device with a reservoir having a polymer matrix and an antimicrobial agent disposed within the polymer matrix. (See Column 6 \P 0097). Additionally the device has a surfactant coating disposed over the reservoir at an outer surface of the device. (See Column 5 \P 0094). It is inherent since the device is inserted within the body it will come into contact with blood.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 5-6 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smothers in view of Vacheethasanee.

Smothers meets the claim limitations as described above but fails to have a surfactant that is a surfactant polymer.

Vacheethasanee discloses surfactant polymers designed to suppress bacterial adhesion on biomaterials. The surfactant polymers include a polymer as claimed in claim 6.

At the time of the invention it would have been obvious to incorporate the surfactant polymer of Vacheethasanee into the invention of Smothers to provide an outer surface with enhanced ability to prevent bacterial adhesion.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smothers.

Smothers meets the claim limitations as described above but fails to the antimicrobial agent being selected from the agents in claims 9-12.

At the time of the invention, it would have been obvious to use any of the above agents since they are equivalents in the art. The motivation would have been to enhance the ability of the device to prevent infection.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smothers.

Smothers meets the claim limitations as described above but fails to disclose the method of implanting the device within the body of a patient for a period of at least 3 months.

At the time of the invention, it would have been obvious to implant the device for at least 3 months. The device of Smothers is disclosed to protect bone fixations devices. It is obvious to one skilled in the art that box fixation devices would obviously be implanted within the body for at least 3 months.

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Allowable Subject Matter

Claims 8 and 13-14 are allowed.

Claims 2-4,7,13-14,16-20,22-26 and 28-30 are objected to as being dependent upon a

rejected base claim, but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The

examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-872-9302 for regular

communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is 703-308-2192.

BRIAN L. CASLER

SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 3700

Catherine Serke **3**. March 10, 2003